AR201-12767

PETA
PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS
501 FRONT STREET
NORFOLK, VA 23510
TEL 757-622-PETA
FAX 757-622-0457

October 11, 2000

The Honorable Carol Browner
Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Comments on "Robust Summary on p-Cumylphenol"

Dear Administrator Browner:

The following comments on the "Robust Summary for p-Cumylphenol" are submitted on behalf of People for the Ethical Treatment of Animals, the Physicians Committee for Responsible Medicine, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These animal protection and environmental organizations have a combined membership of more than nine million Americans.

This p-cumylphenol test plan, submitted by General Electric, is a gross violation of the letter and spirit of the EPA's October 14, 1999, guidance letter to HPV participants, specifically violating seven of the ten major points of the letter. Most glaringly, this is a plan for a single compound, whose testing is specifically delayed by that October 14 letter until November 2001. In its posted letter of clarification, General Electric states that EPA "requested deferment of testing of individual chemicals unless there were reasons for testing sooner than that." This is false: the October letter specifically states that "individual chemicals (i.e., those not proposed for testing in a category) that require further testing on animals ***shall*** be deferred until November 200 1."

Furthermore, this plan violates the original HPV program framework in which sponsors pledge to evaluate the adequacy of existing data and submit robust summaries for the sponsored chemicals. The p-cumylphenol test plan submitted by General Electric ignores existing data and proposes to conduct poorly thought-out tests that provide little useful information on the risk that p-cumylphenol may pose, while causing extensive animal suffering. The plan provides no rationale for the testing and gives no details of the specific procedures that will be used in the testing. It is shocking that a company of General Electric's stature would submit such a shoddy piece of work. The p-cumylphenol test plan is unacceptable from both a technical and regulatory perspective and should have been absolutely rejected by EPA.

The EPA's double standard regarding animal testing is obvious in the EPA's responses to date to proposed test plans. The EPA sets extremely high standards each time a company proposes to use existing data, SAR's, or categories in order to avoid conducting a test. However, the agency does not require any justification if a company wants to use animal tests – even if, as in the General Electric case, the company proposes to test individual chemicals and ignore the October letter. Further, the EPA has required, in each of its test plan comments to date, that companies respond to the EPA within 60 days with a description of how they intend to incorporate the EPA's comments. Yet the EPA makes no such request of General Electric.

For the third time, we reiterate the request made in our August 21 letter to you that the EPA specifically address our concerns and detail how the agency intends to ensure that the spirit and guidelines of the October 14, 1999, letter are followed. Almost two months after our original request, we have not received any response from the EPA regarding this important matter.

Because we anticipate the resubmission of this test plan at a later date, we are providing further comments. I can be reached at (757) 622-7382, ext. 304, or by e-mail at jessicas@peta-online.org. Correspondence should be sent to my attention at the following address: 4800 Baseline Road, #E104-390, Boulder, CO 80305. I look forward to your response on this important issue.

Sincerely,

Jessica T. Sandler, MHS
Federal Agency Liaison

cc: The Honorable Robert C. Smith
The Honorable F. James Sensenbrenner, Jr.
The Honorable Ken Calvert
The Honorable Jerry Costello
Council on Environmental Quality

Comments

This test plan violates the agreement arrived at by Environmental Protection Agency (EPA), the Chemical Manufacturers Association, the Environmental Defense Fund, and animal protection representatives. The following points of the agreement, as outlined in the EPA's October 14, 1999, are violated entirely or in part by the p-cumylphenol test plan:

1. "In analyzing the adequacy of existing data, participants shall conduct a thoughtful, qualitative analysis rather than use a rote checklist approach.

2. Participants shall maximize the use of existing and scientifically adequate data to minimize further testing.

3. Participants shall maximize the use of existing and scientifically appropriate categories of related chemicals and structure activity relationships.

5. Participants are encouraged to use *in vitro* genetic toxicity testing to generate any needed genetic toxicity screening data, unless known chemical properties preclude its use.

6. Consistent with the OECD/SIDS program, participants generally should not develop any new dermal toxicity data.

8. As with all chemicals, before generating new information, participants should further consider whether any additional information obtained would be useful or relevant

9. (b) . . .individual chemicals (i.e., those HPV chemicals not proposed for testing in a category) that require further testing on animals shall be deferred until November 2001 to allow for non-animal test replacements for some SIDS endpoints."

This test plan is proposed for a single chemical (violation of item 9b). Therefore, the test plan must be rejected under the HPV program.

In addition, the proposed test plan is nothing more than a rote reproduction of the checkboxes for each chemical outlined in the original HPV guidance (violation of items 1 and 8). A thoughtful evaluation of the feasibility and necessity of the various tests cannot be conducted without some knowledge of the basic properties or application of the chemical. For example, the utility and application of aquatic toxicity tests cannot be judged without knowledge of the chemical's solubility in water. At a minimum, General Electric needs to state the use of the chemical, the order of testing, the data needed to conduct subsequent tests, and specifically refer to the exact method to be used for each

human health endpoint test. The human health endpoint test information needs to include (at a minimum) whether the tests are *in* vivo or *in vitro,* list the species to be used, outline the exposure method, and list the exposure time. One other technical issue not addressed in the plan is how General Electric plans to analyze for p-cumylphenol when it conducts these tests, since specific analytical techniques may be required for environmentally relevant concentrations.

General Electric has failed to include all the available toxicological data in its test plan. For example, p-cumylphenol is listed by the Food and Drug Administration (FDA) as an approved food contact substance (http://vm.cfsan.fda.gov/~dms/opa-indt.html). In order to apply for FDA approval, the manufacturer typically follows the pre-market notification (PMN) procedure. The toxicology data package for a pre-market notification should contain both a safety narrative (SN) and comprehensive toxicological profile (CTP) of the food contact. The SN should provide the basis for the notifier's determination that the intended use of the food contact substance is safe. The CTP should provide summaries and critical evaluations of all of the available toxicological information pertinent to the safety evaluation of the food contact substance. The toxicology data are public information under the Freedom of Information Act (FOIA), therefore we have filed a FOIA request to obtain any toxicology information on p-cumylphenol. In keeping with the spirit and terms of the October 14, 1999, letter as well as the original HPV framework agreement, General Electric should gather this relevant toxicological data and incorporate it into its robust summary (violation of item 2).

General Electric has also failed to compare p-cumylphenol with other similar chemicals to form a group of phenol compounds (violation of item 3). The composition of p-cumylphenol is similar to a range of substituted phenolic compounds and complex mixed phenolic industrial streams, and could justifiably be included in a larger substituted or alkylphenol group. As has been referenced in previous comments', we are concerned that a specific company or industry may not cooperate in the development of categories, as stated in the guidance. It is critical that EPA play a leadership role in developing this cross fertilization, so that unnecessary, expensive, and poorly conceived testing is avoided.

The test plan fails to provide a justification for conducting an *in vivo* genetic toxicity study, even though only *in* vitro tests should be used to generate any needed genetic toxicity screening data, unless known chemical properties preclude their use (violation of item 5).

The test plan calls for a dermal toxicity study, which is also proscribed in the October 14 letter (violation of item 6).

[1] PETA letter to Carol Browner dated August 2 1, 2000

Conclusions

In short, General Electric has submitted a greatly flawed workplan both from a technical and regulatory perspective. It is astounding that a company of the stature of General Electric would submit such a poorly researched, poorly developed test plan. The EPA must require that p-cumylphenol be considered for inclusion into a larger substituted phenol group and that General Electric provide additional existing data on p-cumylphenol toxicity and chemistry. The workplan must have clear documentation of the methods of testing and provide for the evolution of the experimental plan based on early physical and chemical determinations about the compound. As it stands, the EPA must reject this workplan in its entirety due to its blatant violations of the October agreement and the original HPV framework.